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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/014,927

10/23/2001

Andrea Barta

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11/03/2004

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EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,927

Applicant(s)

BARTA ET AL.

Examiner

Stuart F. Baum

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 62-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 8/12/2004 has been entered.
Claims 1-61 have been canceled.
2. Claims 62-102 are pending and examined in the present office action.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Foreign Priority

5. The Office acknowledges Applicants' intention to submit a certified copy of Austrian Application No. A 727/99 filed April 23, 1999, in due course.

Indefiniteness

6. Claims 62 and 64-102 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

Claim 62 remains indefinite in the recitation "atSRp30 protein". The sole designation of an amino acid sequence by "atSRp30 protein" is arbitrary and creates ambiguity in the claims. For example, the amino acid sequence in this application could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to designate a different amino acid sequence. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to a specific SEQ ID NO would

obviate this rejection. All subsequent recitations of “atSRp30 protein” are also rejected. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/9/2004. Applicant’s arguments filed 8/12/2004 have been fully considered but they are not persuasive.

Applicants contend that the term “atSRp30 protein” is fully described and explained throughout the specification. Applicants specifically reference page 22, line 14 through to page 27, line 8, and lines 14-17. Applicants contend that one of ordinary skill in the art would understand the term “atSRp30 protein” (page 15, 2nd and 3rd paragraphs).

The Office contends that Applicants have not defined “atSRp30 protein”. Applicants’ referenced pages only describe a comparison of atSRp30 to other SR proteins, and RNA distribution and alternative splicing forms of atSRp30 and atSRp34/SR1. Applicants do not explicitly define an “atSRp30 protein” in terms of an amino acid sequence.

In claim 62, the metes and bounds of “being derived from atSRp30 protein” have not been defined. Applicants have not specified what encompasses “being derived from atSRp30”. Applicants have not disclosed how one measures the derivation of a protein from another protein and what parameters constitute a protein being derived from atSRp30 and what parameters constitute a protein not being derived from atSRp30. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/9/2004. Applicant’s arguments filed 8/12/2004 have been fully considered but they are not persuasive.

Applicants contend that a person of ordinary skill in the art understands the meaning of the term “derived”. Applicants contend that this term is used in the specification in a number of

instances. Applicants contend a person of ordinary skill in the art “would understand what is claimed when read in light of the specification” (page 16, last paragraph).

The Office contends that Applicants have not defined “derived” when used in the phrase “being derived from atSRp30 protein”. Applicants have not specified where in the specification derived is used. The Office contends that using the term in the specification does not make the term or a phrase which uses this term definite.

In claim 65, the metes and bounds of “atSRp30 activity” have not been defined. Applicants have not defined the specific activity to which they are referring. The specification does not explicitly state the function or activity of the atSRp30 protein, i.e., if the atSRp30 protein is involved in splicing mRNA, what sequence of mRNA does it bind to or splice? This rejection is maintained for the reasons of record set forth in the Official action mailed 4/9/2004. Applicant’s arguments filed 8/12/2004 have been fully considered but they are not persuasive.

Applicants contend that claim 64 makes it clear that the “activity” referred to is “splicing factor activity in plant”. Applicants contend that the specification also explains that, in non-limiting embodiments, atSRp30 modulates alternative splicing of pre-mRNA *in vivo*. Applicants also contend that a part of the rejection is without merit. In particular, the phrase “what sequence of mRNA does [atSRp30 protein] bind to or splice” is not indefinite, but broad. Applicants note “Breadth of a claim is not to be equated with indefiniteness” (page 17 3rd and 4th paragraphs).

The Office contends that the rejection is directed to “atSRp30 activity” as recited in claim 65. Claim 64, from which claim 65 is dependent, describes a recombinant nucleic acid molecule of claim 62, wherein the nucleic acid molecule has specific identities to other molecules, but

nowhere in the claims does Applicant explicitly define the activity of atSRp30. In fact, Applicants disclose that “The specification also explains that, in non-limiting embodiments, atSRp30 modulates (emphasis added) alternative splicing of pre-mRNA *in vivo*” (see above). Is the activity of atSRp30 to modulate splicing or act as a splice factor? The Office contends, that in regards to the sequence of mRNA to which atSRp30 binds, that question was only given as an example to be used to define the potential activity of Applicants’ invention.

Claim 65 remains indefinite in the recitation “atSRp34/SR1 protein”. The sole designation of an amino acid sequence by “atSRp34/SR1 protein” is arbitrary and creates ambiguity in the claims. For example, the amino acid sequence in this application could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to designate a different amino acid sequence. If either event occurs, one’s ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to a specific SEQ ID NO would obviate this rejection. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/9/2004. Applicant’s arguments filed 8/12/2004 have been fully considered but they are not persuasive.

Applicants contend that the present rejection appears to be analogous to the rejection addressed in the section above. Applicants contend that the arguments made in the section above have been incorporated into this section by reference (page 18, 4th paragraph).

The Office contends that Applicants have not defined “atSRp34/SR1 protein”. Applicants’ referenced pages only describe a comparison of atSRp30 to other SR proteins, and

RNA distribution and alternative splicing forms of atSRp30 and atSRp34/SR1. Applicants do not explicitly define an "atSRp34/SR1 protein" in terms of an amino acid sequence.

Written Description

7. Claims 62, and 64-102 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/9/2004. Applicant's arguments filed 8/12/2004 have been fully considered but they are not persuasive.

Applicants contend that the specification provides written description for claims drawn to a nucleic acid sequence comprising SEQ ID NO:18. A complete listing of SEQ ID NO:18 can be found in the sequence listing (page 21, 4th paragraph).

The office contends that for claims drawn to a nucleic acid sequence comprising SEQ ID NO:18, Applicants have fulfilled the written description requirement.

Applicants contend, that for claims drawn to a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19, or comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19, or corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*, Applicants have fulfilled the written description. Applicants contend that all the recited limitations are recited in the specification and Applicant has reiterated the specific recitations in Applicants' response and

included page numbers as to where the recitations can be found in the specification (see pages 21-23, "The specification provides written description for element [2]"). Applicants also contend that the nucleic acid and amino acid sequences listed in Figure 1A correspond to SEQ ID NO:18 and 19, respectively (page 21, last paragraph). In summary, Applicants contend that the disclosure of the nucleic acid and amino acid sequence listed in Figure 1A, which corresponds to SEQ ID NO:18 and 19, is sufficient to fulfill the written description requirement for the claims recited previously.

The Office contends, that for the specified claims, a disclosure of one nucleic acid sequence encoding one amino acid sequence is not sufficient to fulfill the written description requirement. The Office contends that Applicants have not disclosed a representative number of sequences encoding a protein having splicing factor activity in plant, wherein said protein comprises more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID NO:19, or a representative number of sequences encoding a protein from another plant other than Arabidopsis, wherein said protein corresponds to or being derived from atSRp30. Furthermore, Applicants have not described structural features that are common to and unique to the claimed genus of DNAs. Applicants merely describe a single DNA and amino sequence of SEQ ID NO:18 and 19, respectively. Without said description, Applicants have not fulfilled the written description requirements that entitles Applicants to variants of SEQ ID NO:18 that fall within Applicants' claim limitations.

Applicants contend that for claims drawn to a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof, is described in Applicants' specification. Applicants contend that the nucleic acid sequence in Figure 1A

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corresponds to SEQ ID NO:18 and that this language provides written description for the recited claims. Applicants contend that the nucleic acid sequence of SEQ ID NO:18 defines the structural features for the claimed invention (paragraph bridging pages 23 and 24, and page 24, 1st full paragraph).

The Office contends that Applicants have not disclosed a representative number of sequences that binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof. Furthermore, Applicants have not described structural features that are common to and unique to the claimed genus of DNAs. Applicants have also not recited in the claims that the specified nucleic acid molecules encode a protein with the same activity as the protein encoded by SEQ ID NO:18. Applicants merely describe a single DNA and amino sequence of SEQ ID NO:18 and 19, respectively. Without said description, Applicants have not fulfilled the written description requirements that entitles Applicants to variants of SEQ ID NO:18 that fall within Applicants' claim limitations.

Enablement

8. Claims 62-102 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/9/2004. Applicant's arguments filed 8/12/2004 have been fully considered but they are not persuasive.

Applicants contend that for claims drawn to a recombinant nucleic acid molecule comprising a nucleic acid sequence comprising SEQ ID NO:18, Applicants are enabled. Applicants contend, Figure 1A contains a mistake in the nucleotide sequence numbering. The sequence length in Figure 1A is 4044 which corresponds to the complete sequence listing number in SEQ ID NO:18. Applicants also note that the sequence of atSRp30 submitted to the EMBL database contains an additional 1120 nucleotides upstream of SEQ ID NO:18. These additional nucleotides were omitted from Figure 1A because SEQ ID NO:18 contains the necessary nucleotide sequence that forms the basis of the data presented in this Application (page 26, 3rd paragraph). Applicants contend that the specification discloses how to use SEQ ID NO:18 for over-expression in a plants (page 26, last paragraph).

The office contends that Applicants are not enabled for claims drawn to SEQ ID NO:18 because Applicants have not disclosed the start and stop codons associated with SEQ ID NO:18 that encodes SEQ ID NO:19. As stated in the office action mailed 4/9/2004, SEQ ID NO:18 does not encode the full length SEQ ID NO:19 polypeptide (a copy of the sequence search results were included with the office action). Given that SEQ ID NO:18 does not encode the full length polypeptide of SEQ ID NO:19, one skilled in the art would not know the identity of the polypeptide that is Applicants' invention, or which nucleic acid encodes said polypeptide. Applicants are invited to submit a 1.132 declaration supplying the necessary information.

Applicants contend that for claims drawn to a nucleic acid sequence encoding a protein comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of SEQ ID NO:19, or to a protein corresponding to or being derived from atSRp30 protein from a plant other than Arabidopsis, the invention is enabled. Applicants contend that the

specification enables “a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID NO:19” (page 27, 4th paragraph). Applicants contend that the specification teaches how to make SEQ ID NO:19 from a nucleic acid, how a cDNA can be expressed in bacteria to obtain the polypeptide of SEQ ID NO:19 and how SEQ ID NO:19 can be used to affect plant development (*ibid*). Applicants contend that for proteins exhibiting less than 100% sequence identity to SEQ ID NO:19, a person of ordinary skill in the art would be able to determine which nucleic acids would encode said protein. Applicants contend that by reference to a standard codon chart, this can be achieved (page 28, 1st full paragraph). Applicants contend that page 31, line 18 to page 34, line 19, provides guidance for such claims (*ibid*).

The Office contends that for claims drawn to SEQ ID NO:18 encoding SEQ ID NO:19 Applicants are not enabled because according to the sequence search results of DNA encoding SEQ ID NO:19, SEQ ID NO:18 does not encode the full length polypeptide of SEQ ID NO:19. It is not clear which nucleic acid sequence Applicants used for the disclosure on pages 31 to 34. For claims drawn to nucleic acid sequences encoding a polypeptide exhibiting less than 100% sequence identity with SEQ ID NO:19, Applicants are also not enabled. Applicants do not disclose any sequence that encodes a polypeptide exhibiting less than 100% sequence identity to SEQ ID NO:19 that has the same activity as SEQ ID NO:19. Applicants do not teach one of ordinary skill in the art which amino acids of SEQ ID NO:19 are required for the activity of the protein and which amino acids can be substituted, deleted or rearranged and still produce a protein with the same activity as the protein whose sequence is set forth in SEQ ID NO:19. In short, Applicants have not taught the conserved domains of the polypeptide that are required for

the activity of the polypeptide. Referencing a standard codon chart will not overcome this deficiency.

Applicants contend that for claims drawn to a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof, Applicant is enabled. Applicants contend that they teach how to make and use said nucleic acids without undue experimentation. Applicants contend that they teach the full length sequence of SEQ ID NO:18 and that a person of ordinary skill in the art knows that Adenine hybridizes with either Thymine or Uracil and Guanine hybridizes with Cytosine (page 29, 1st and 2nd full paragraphs).

The Office contends that Applicants have not disclosed nucleic acid sequences that encode a polypeptide exhibiting less than 100% sequence identity with SEQ ID NO:19, and Applicant has not disclosed a sequence that hybridizes with the complement of SEQ ID NO:18 that encodes a polypeptide with the same activity as the protein whose amino acid sequence is set forth in SEQ ID NO:19. The office contends that one of ordinary skill in the art would know that Adenine forms hydrogen bonds with either Thymine or Uracil and Guanine forms hydrogen bonds with Cytosine. The issue at hand, is that Applicants have not taught an example of sequences that hybridize with the complement of SEQ ID NO:18 and encode a polypeptide with the same activity as SEQ ID NO:19 or Applicants have not taught the conserved domains of the polypeptide whose sequence is set forth in SEQ ID NO:19.

Applicants contend that enablement must bear only a reasonably relationship to the scope of the claims. See *In re Fisher*, 166 U.S.P.Q. 18, 24 (CCPA 1970).

The Office contends that the scope of the claims must be commensurate with the scope of the disclosure. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970), which teaches that the

allegedly pioneering nature of an invention does not obviate the need for "a reasonable correlation" between the scope of the claims and "the scope of enablement provided by the specification", wherein "the scope of enablement obviously varies conversely with the degree of unpredictability of the factors involved" in "cases involving unpredictable factors, such as most chemical reactions and physiological activities".

35 USC § 102

9. Claims 62, 64-67, 69-86, and 93-102 remain rejected under 35 U.S.C. 102(b) as being anticipated by Meyerowitz et al (April, 1998, U.S. Patent Number 5,744,693). This rejection is maintained for the reasons of record set forth in the Official action mailed 4/9/2004. Applicant's arguments filed 8/12/2004 have been fully considered but they are not persuasive.

Applicants contend that the rejection fails to identify where Meyerowitz et al teach the elements claimed in the present invention. For example, claim 62 recites, in part, "a nucleic acid sequence comprising SEQ ID NO:18". Claim 62 also recites a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19, or comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19, or corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana* (page 32, 1st full paragraph).

The Office contends that claim 62 comprises various elements claiming different scope of invention, all of which are recited in the alternative, which means Meyerowitz et al only has to teach one of the elements for the claim to be anticipated. The Meyerowitz et al reference teaches

those elements of claim 62 directed towards an encoded protein derived from atSRp30. Given the 112 2nd paragraph rejection for “derived” and “atSRp30 activity”, the office interprets these terms to read on any protein, and as such, the Meyerowitz et al reference anticipates the claimed invention.

10. Claims 62, 66-68 and 76-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazar (April, 1993, NCBI Accession Number M98340). This rejection is maintained for the reasons of record set forth in the Official action mailed 4/9/2004. Applicant’s arguments filed 8/12/2004 have been fully considered but they are not persuasive.

Applicants contend that Lazar does not teach or suggest every element of claims 62, 66-68, 76-77. Applicants contend that Lazar does not teach a nucleic acid sequence...comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID NO:19 (page 33, 2nd full paragraph).

The Office contends that claim 62 comprises various elements claiming different scope of invention, all of which are recited in the alternative, which means Lazar only has to teach one of the elements for the claim to be anticipated. The Lazar reference anticipates claims drawn to a nucleic acid sequence that binds to a nucleic acid molecule comprising SEQ ID NO:18 under stringent conditions wherein the nucleic acid molecule encodes a splice protein active in plants, and as such, Lazar anticipates the claimed invention.

11. Claims 62-70, 73-78, 81-84, 87-90, and 93-100 are rejected under 35 U.S.C. 102(b) as being anticipated by Lopato et al (April 15, 1999, Genes & Development 13:987-1001; listed in

IDS). This rejection is maintained for the reasons of record set forth in the Official action mailed 4/9/2004. Applicant's arguments filed 8/12/2004 have been fully considered but they are not persuasive.

Applicants contend that the Lopato et al reference was published on April 15, 1999, but was actually mailed to the public on April 23, 1999. Applicants include a letter from the publisher stating that the April 15, 1999 issue of Genes and Development was released for mailing on April 23, 1999. Applicants claim foreign priority back to April 23, 1999 and will submit a certified copy of said reference in due course (last paragraph on page 33, page 34, 1st paragraph).

The office acknowledges Applicants' intent to submit the certified document which will make moot the Lopato et al reference. The rejection is maintained until receipt of Austrian Application A 727/99 filed 4/23/1999.

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
October 27, 2004

A handwritten signature in black ink, appearing to read "Amy Nelson", is positioned above the typed name and title of the supervisor.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600